

**IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF OKLAHOMA**

SUSAN NEVOLAS,)	
)	
Plaintiff,)	
)	
vs.)	Case No. CIV-15-894-M
)	
BOSTON SCIENTIFIC CORPORATION,)	
)	
Defendant.)	

ORDER

Before the Court is defendant's Motion to Dismiss Plaintiff's Amended Complaint, filed December 7, 2015. On December 28, 2015, plaintiff filed her response, and on January 11, 2016, defendant filed its reply.

I. Introduction

Plaintiff has brought the instant action to recover damages for injuries she allegedly sustained after she was implanted in September 2012 with a PRECISION SPINAL CORD STIMULATOR, Model SC-1010C ("Stimulator"), manufactured by defendant Boston Scientific Corporation. The Stimulator is a Class III Medical Device. Plaintiff alleges that the Stimulator malfunctioned because it was defective and the defect caused the Stimulator to run hot and/or overheat and/or operate at abnormally high temperatures. *See* Plaintiff's Amended Complaint [docket no. 18] at ¶¶ 15-16. Plaintiff further alleges that because the defect could not be corrected by "reprogramming," she was required to undergo an additional surgery to remove the original device. Defendant now moves the Court to dismiss plaintiff's Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

II. Standard for Dismissal

Regarding the standard for determining whether to dismiss a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), the United States Supreme Court has held:

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a “probability requirement,” but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant’s liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (internal quotations and citations omitted). Further, “where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not shown - that the pleader is entitled to relief.” *Id.* at 679 (internal quotations and citations omitted). Additionally, “[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertion[s] devoid of further factual enhancement.” *Id.* at 678 (internal quotations and citations omitted). A court “must determine whether the complaint sufficiently alleges facts supporting all the elements necessary to establish an entitlement to relief under the legal theory proposed.” *Lane v. Simon*, 495 F.3d 1182, 1186 (10th Cir. 2007) (internal quotations and citation omitted). Finally, “[a] court reviewing the sufficiency of a complaint presumes all of plaintiff’s factual allegations are true and construes them in the light most favorable to the plaintiff.” *Hall v. Bellmon*, 935 F.2d 1106, 1109 (10th Cir. 1991).

III. Discussion

Defendant asserts that plaintiff's Amended Complaint should be dismissed for the following two independent reasons: (1) because federal law expressly preempts plaintiff's claims related to the Stimulator, and (2) because plaintiff fails to plead sufficient facts under Federal Rule of Civil Procedure 8 to plausibly support her negligence-based claims. Plaintiff contends that her claims are not preempted by federal law and meet the pleading standard required by Rule 8.

It is undisputed that the Stimulator is subject to the United States Food and Drug Administration's ("FDA") intensive Premarket Approval ("PMA") process and that the FDA approved the Stimulator. By passing the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360, the United States Congress ceded exclusive regulatory authority over medical devices to the FDA because it determined that satisfaction of the FDA's PMA requirements are adequate, as a matter of law, to safeguard the American public in its use of medical devices. The MDA includes an express preemption provision that states:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).¹ In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the United States Supreme Court employed a two-step analysis for determining whether state law claims are preempted under § 360k(a). First, the Supreme Court considered whether PMA of a medical device by the FDA

¹The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from preemption.

imposes federal “requirements” under the MDA. *See Riegel*, 552 U.S. at 321-23. The Court concluded that PMA imposes federal “requirements” within the meaning of the MDA. *See id.* at 322-23. Second, the Supreme Court considered whether the state common law claims would impose requirements “different from, or in addition to” the requirements imposed by the PMA process and that relate to safety and effectiveness. *See id.* at 322-23. The Court concluded that the plaintiffs’ state common law claims for strict products liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the device would impose requirements “different from, or in addition to” the requirements imposed by the PMA process. *Id.* at 323. When determining whether a state requirement is “in addition to” the requirements imposed by federal law, courts have found “[w]here a federal requirement permits a course of conduct and the state makes its obligatory, the state’s requirement is in addition to the federal requirement and thus is preempted.” *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010) (internal quotations and citation omitted).

However, the Supreme Court has made clear that “[s]tate requirements are pre-empted under the MDA only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” *Riegel*, 552 U.S. at 330.

In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are “*genuinely* equivalent.” State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.

Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300 (8th Cir. 2011) (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)) (emphasis in original). Further, “[t]o properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated.” *Id.* at 1301 (internal quotations and citation omitted). “Plaintiffs must also allege a link between the failure to comply and the alleged injury.” *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 204 (W.D.N.Y. 2011).

In her response, plaintiff asserts that she has sufficiently pled parallel claims to survive federal law preemption. Specifically, plaintiff alleges that her Amended Complaint alleges the state common law and federal regulations she contends defendant violated and that at this point in litigation, it is impossible for her to plead with further specificity given the limited amount of information that is publicly available.

Having carefully reviewed plaintiff’s Amended Complaint, the Court finds that plaintiff has failed to state any parallel claims to survive federal law preemption. Specifically, the Court finds that in her Amended Complaint, plaintiff simply makes numerous conclusory allegations, devoid of any factual support, that defendant violated in unspecified ways various federal regulations and federal manufacturing requirements. For example, plaintiff alleges:

33. The device which was required to be removed and replaced in August 2013 malfunctioned (as defined by 21 CFR § 803.3(k)). The malfunction occurred as a result of the negligence of the Defendant in the design, manufacture, testing, selection/supervision of suppliers or otherwise failing to manufacture the device as required by the FDA.

34. Because of manufacturing defects, the device implanted in Plaintiff was defective and hazardous to patients including, but not limited to, Plaintiff.

35. Defendant failed to follow the established protocol for manufacturing the device in violation of 21 CFR § 814.80.

36. The quality control requirements and/or current good manufacturing practice requirements for the manufacturing of the device were not followed by Defendant in violation of 21 CFR § 820.

37. The Defendant was negligent *per se* in choosing to not following the applicable FDA requirements for the proper manufacturing of the device.

* * *

40. The Defendant was negligent in choosing to not warn consumers, medical professionals and the FDA of the defects in the device which caused it to malfunction, rendered it defective and caused/contributed to injuries and damages to the consuming public including, but not limited to the Plaintiff. Defendants' actions in this regard were intentional and deliberate, all in violation of FDA requirements including, but not limited to 21 CFR §§ 803, 860.

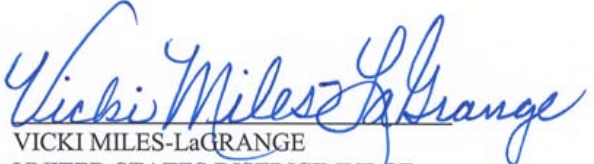
Plaintiff's Amended Complaint at ¶¶ 33-37, 40.

The Court recognizes that individuals in plaintiff's position are handicapped because "[i]n the case of Class III medical devices, potentially valuable information related to PMA is kept confidential as a matter of federal law and formal discovery may be required before a plaintiff can fairly be expected to identify specific defects." *Comella v. Smith & Nephew, Inc.*, No. 13 C 1850, 2013 WL 6504427, at *3 (N.D. Ill. Dec. 11, 2013) (internal citation omitted). "However, more is required to make out a parallel claim than conclusory statements that a defendant violated multiple regulations." *Swisher v. Stryker Corp.*, No. CIV-14-0028-HE, 2014 WL 1153716, at *2 (W.D. Okla. Mar. 14, 2014). The Court finds plaintiff's allegations that defendant was required to follow non-specific federal regulations and current good manufacturing practice requirements, which are applicable to all manufacturers of all medical devices, are insufficient to state a plausible parallel claim upon which relief can be granted. "Allowing a plaintiff to plead non-specific regulations as a basis for a parallel claim is inconsistent with the Supreme Court's reasoning in *Riegel*, as well as the pleading requirements articulated in *Twombly* [and] *Iqbal*." *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 495 (W.D. Pa. 2012).

IV. Conclusion

Accordingly, for the reasons set forth above, the Court GRANTS defendant's Motion to Dismiss Plaintiff's Amended Complaint [docket no. 25] and DISMISSES plaintiff's Amended Complaint. However, as it is possible plaintiff may be able to correct the pleading deficiencies, the Court GRANTS plaintiff leave to file a second amended complaint by February 15, 2016.

IT IS SO ORDERED this 28th day of January, 2016.


VICKI MILES-LaGRANGE
UNITED STATES DISTRICT JUDGE